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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,728	06/19/2001	Clifford J. Dwyer	CRD-0940	3625

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,728

Applicant(s)

DWYER ET AL.

Examiner

Cheryl L. Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3 6) ☐ Other: _____

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DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 60. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 70. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. It is suggested to change 70 to 60 in the figures.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "18" and "26" have both been used to designate distal end of shaft. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
 5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 6. Claim 1 recites the limitation "the self-expanding stent" in line 4. There is insufficient antecedent basis for this limitation in the claim. A self-expanding stent has not been positively claimed in the body of the claim. It is suggested to change "the self-expanding stent" to recite --a self-expanding stent--.
- Claims 2-7 depend upon parent claim 1 and inherit all problems associated with the parent claim.

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7. Claim 8 recites the limitation "the self-expanding stent" in line 4. There is insufficient antecedent basis for this limitation in the claim. A self-expanding stent has not been positively claimed in the body of the claim. It is suggested to change "the self-expanding stent" to recite --a self-expanding stent--.

Claims 9-15 depend upon parent claim 8, and inherit all problems associated with the parent claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

9. Claims 1-2 and 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al (USPN 6,425,898 B1). Wilson discloses a delivery apparatus, which includes all limitations recited in the claims. Wilson discloses a delivery apparatus (1) for a self-expanding stent (50) comprising a shaft (10), having a guidewire lumen (28) and a stent bed (24), a sheath (40) having an enlarged section (col.4, lines 35-38) coaxial with the stent bed (24), the sheath formed from an inner polymeric layer (48), an outer polymeric layer (72), and a wire reinforcement layer (70), which extends between the inner and outer layers (fig.8). Wilson discloses an inner polymeric layer comprising PTFE and an outer layer comprising NYLON (col.7, lines 65-66).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (USPN 6,425,898 B1) in view of Truckai (USPN 5,176,660). Wilson discloses a delivery apparatus with a wire reinforced sheath substantially as claimed. Wilson does not disclose however, wires having a rectangular cross section and dimensions for such wires. Referring to claims 3-4, Truckai teaches a layered delivery sheath (catheter, 10) having flat wire reinforcement (16) with rectangular cross-sections (fig.5) with specific dimensions (col.2, lines 60-61; col.4, lines 1-5, 39) in order to increase stiffness and provide a low-profile smooth sheath during delivery (col.2, lines 15-21, 42-43; col.4, lines 1-7; col.5, lines 11-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Truckai's teaching of a sheath comprising a flat rectangular wire, with Wilson's sheath and delivery apparatus in order to provide a low-profile smooth stiff delivery sheath.

Referring to claim 5, Wilson discloses wire reinforcement arranged in a braided configuration (col.7, lines 65-67).

12. Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (USPN 6,425,898 B1) in view of Kocak (USPN 4,705,511). Wilson discloses a delivery apparatus substantially as claimed. Referring to claims 8 and 15, Wilson discloses a delivery apparatus (1) for a self-expanding stent (50) comprising a shaft (10), having a guidewire lumen (28) and a stent bed (24), a sheath (40) having an enlarged section (col.4, lines 35-38) coaxial with the stent bed (24), the sheath formed from an inner polymeric layer (48), an outer polymeric layer (72), and a wire reinforcement layer (70). Wilson does not however, disclose a lubricious coating on an inner polymeric layer. Kocak teaches in the same field of endeavor, a delivery sheath (38, 138) for introducing catheters and medical devices to the vascular system (col.4, lines 15-16), the sheath having a wire reinforcing layer (40, 140), polymeric layers (42, 142) and additional lubricious coating (41, 141) in order to provide a smooth, low friction surface (col.5, lines 56-61). Kocak discloses coating materials comprising PTFE or silicone (col.5, lines 65-67; col.3,

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lines 8-17; col.4, line 59; col.4, lines 63-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kocak's teaching of lubricous coatings such as silicone on a delivery sheath, with Wilson's delivery sheath in order to provide a sheath with a smooth, low friction surface.

Referring to claim 9, Wilson discloses a reinforcement layer sandwiched between an inner and outer polymeric layer and extending the length of the sheath (fig.8).

Referring to claims 10-11, Wilson discloses a sheath having a wire reinforcement layer, however does not disclose a rectangular cross section for the wire and dimensions for such a wire. Kocak teaches in the same field of endeavor, a wire reinforcement layer having a rectangular cross section with specific dimensions and made of stainless steel in order to provide a low smooth profile and increased flexibility (fig.5, 140; col.7, lines 16-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kocak's teaching of a dimensioned rectangular cross section stainless steel wire reinforcement layer of a sheath, with Wilson's sheath reinforcement layer in order to provide a low smooth profile with flexibility.

Referring to claim 12, Wilson discloses wire reinforcement arranged in a braided configuration (col.7, lines 65-67).

Referring to claims 13 and 14, Wilson discloses an inner polymeric layer comprising PTFE and an outer layer comprising NYLON (col.7, lines 65-66).

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Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

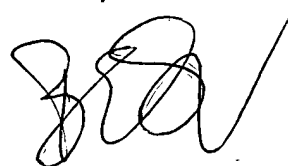
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

September 11, 2002



BRUCE SNOW
PRIMARY EXAMINER